

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER <b>RO4126US (#90568)</b>
INTERNATIONAL APPLICATION NO. <b>PCT/EP2004/006659</b>	INTERNATIONAL FILING DATE <b>19 June 2004 (19.06.2004)</b>	U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/562422</b>
PRIORITY DATE CLAIMED <b>27 June 2003 (27.06.2003)</b>		
TITLE OF INVENTION <b>Transmucosal Form of Administration with Reduced Mucosal Irritation</b>		
APPLICANT(S) FOR DO/EO/US <b>RADEMACHER, Tina and VON FALKENHAUSEN, Christian</b>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</li> <li>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))             <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).             <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input checked="" type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol>		
Items 11 to 20 below concern document(s) or information included:		
<ol style="list-style-type: none"> <li>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>13. <input checked="" type="checkbox"/> A preliminary amendment.</li> <li>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</li> <li>15. <input checked="" type="checkbox"/> A substitute specification.</li> <li>16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter. (Power of Attorney included w/Declaration - #9 above)</li> <li>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</li> <li>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</li> <li>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> </ol>		

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20. Other items or information: Publication No. WO 2005/000263 (first page only); PCT/ISA/210; Written Opinion; Response to Written Opinion; IPER with annexes; return postcard receipt					
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))					
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 All other situations.....\$200				\$ 200.00	
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))					
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400 All other situations.....\$500				\$ 400.00	
TOTAL OF 21, 22 and 23 =				900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
17 - 100 =	-83 /50 =		x \$250	\$ 0.00	
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$ 0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	32 - 20 =	12	x \$ 50	\$ 600.00	
Independent claims	3 - 3 =	0	x \$200	\$ 0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$ 0.00	
TOTAL OF ABOVE CALCULATIONS =				\$ 1,500.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				0.00	
SUBTOTAL =				\$ 1,500.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$ 0.00	
TOTAL NATIONAL FEE =				\$ 1,500.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ 40.00	
TOTAL FEES ENCLOSED =				\$ 1,540.00	
				Amount to be refunded:	\$
				Amount to be charged	\$

10/562422

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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IAP9 Rec'd PCT/PTO 27 DEC 2005

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 08-2441. A duplicate copy of this sheet is enclosed.
- d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

## SEND ALL CORRESPONDENCE TO:

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*Sean Mellino*

SIGNATURE

Sean Mellino

NAME

48,817

REGISTRATION NUMBER

## EXPRESS MAIL CERTIFICATION UNDER 37 CFR 1.10

"Express Mail" label number: EV713319914US

Date of deposit

*December 27, 2005*

I hereby certify that the paper(s) identified above, and any document(s) referred to as attached hereto, is being deposited with the United States Postal Service on the date indicated in an envelope as "Express Mail Post Office to Addressee" and is addressed: Mail Stop PCT,

Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, 22313-1450.

Christine Kotran

*Christine Kotran*